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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,790	03/22/2001	Keith D. Allen	R-855	5557

26619 7590 04/21/2003

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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/816,790

Applicant(s)

ALLEN ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-16, 22-25 and 40-51 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 22-25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-43 and 50 is/are allowed.
- 6) ☒ Claim(s) 44-49, 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 11-16, 22-25 and 40-51 are pending in the application.

Claims 11-16 and 22-25 are withdrawn from consideration for being directed to non-elected subject matter. Claims 40-51 are currently under examination.

This Office Action is in response to the Amendment filed on 3/4/03.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/4/03 has been entered.

#### ***Response to Amendment***

The rejection of claims 31-39 under 35 U.S.C. 112 1<sup>st</sup> paragraph is moot in light of Applicants' cancellation of the claims.

The rejection of claims 26-30 under 35 U.S.C. 103 (a) is moot in light of Applicants' cancellation of the claims.

Claims 44-49 and 51 are rejected under 35 U.S.C. 112 1<sup>st</sup> paragraph (scope of enablement) for reasons discussed below.

*Response to Arguments*

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-49 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse whose genome comprises a homozygous disruption of the endogenous sulfotransferase gene, wherein said transgenic mouse lacks production of the functional sulfotransferase protein, and exhibits a behavioral abnormality, does not reasonably provide enablement for a transgenic mouse whose genome comprises a heterozygous disruption of the endogenous sulfotransferase gene. Further, the specification does not support the enablement of a cell or tissue isolated from the transgenic mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The newly added claims 44-49 and 51 are rejected for same reasons as applied to now cancelled claims 31-39 that set forth of the record mailed on 10/23/03 (see pages 3-5).

The nature of the invention is a transgenic mouse comprising a disruption in the sulfotransferase gene, wherein said transgenic mouse lacks production of the functional sulfotransferase protein and exhibits a behavioral abnormality. The invention is further drawn to a cell or tissue isolated from said mouse.

The specification discloses that only the homozygous knockout mice exhibit a behavioral abnormality including aggressive behavior, hyperactivity and decreased anxiety (see page 59-60). The specification fails to teach whether transgenic mice having heterozygous disruption of the sulfotransferase gene also exhibit same phenotype as the homozygous transgenic mice.

Claims 44-49 encompass heterozygous mouse. The heterozygous mouse comprises one allele having a normal sulfotransferase gene; hence it expresses functional sulfotransferase protein. Therefore, the heterozygous mouse would not be expected to have the phenotype of behavioral abnormality as the homozygous mouse. The claims recite that the transgenic mouse "lack production of functional sulfotransferase protein." The specification does not teach how to make a transgenic mouse having heterozygous disruption of the sulfotransferase gene and lacks functional sulfotransferase protein. The specification also fails to teach how to use a transgenic mouse without the disclosed phenotype. Further, the specification does not teach how to use a cell or tissue isolated from said mouse. The phenotype of the transgenic mouse would not be displayed by a tissue or cell isolated from said mouse because the behavioral abnormality of a cell or tissue cannot be determined by any of the method disclosed in the specification.

Therefore, one skilled of art would have to engage in undue experimentation to determine how to make and use the invention in commensurate with the scope of the claims.

This rejection can be overcome by limiting the claims to a homozygous mouse.

Claims 40-43 and 50 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
April 18, 2003

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER